

# Local Supply Issues – Clenil® Modulite® 100 microgram Metered- Dose Inhaler (MDI)

Updated: 1st April 2020

## Description of product affected

- Clenil® Modulite® 100microgram MDI contain the active ingredient beclometasone dipropionate within a pressurised inhalation solution<sup>1</sup>.
- Clenil® Modulite® is indicated for the prophylactic management of mild, moderate, or severe asthma in **adults or children**<sup>1</sup>:
  - *Mild asthma* - Patients requiring intermittent symptomatic bronchodilator asthma medication on a regular basis.
  - *Moderate asthma* - Patients with unstable or worsening asthma despite prophylactic therapy or bronchodilator alone.
  - *Severe asthma* - Patients with severe chronic asthma and those who are dependent on systemic corticosteroids for adequate control of symptoms.
- Clenil® Modulite® is available in the following strengths: 50microgram, 100microgram, 200microgram and 250microgram per actuation<sup>1</sup>.
- **Please note that the 200mcg and 250mcg strengths are not licensed for use in children.**

## Background

### Update from DHSC regarding the Clenil inhaler range (issued 30/03/2020):

- Chiesi have experienced large increases in demand on their inhaler range over the past two weeks.
- Chiesi are supplying product to wholesalers in line with historic demand to ensure stocks continue to remain available.
- Health care professionals and patients are reminded to only prescribe and order what they need during this time to ensure that all patients can continue to access their medicines.
- Chiesi have confirmed they have stock available of the following Clenil MDI inhalers with the wholesales AAH, Alliance Healthcare and Phoenix with further deliveries expected on a weekly basis:
  - 50microgram
  - 200microgram
  - 250microgram
- Clenil 100microgram MDI inhalers have experienced a delay in their production due to an issue with the actuators for the device.
- Chiesi anticipate further stocks to become available towards the end of the w/c 30th March 2020.

## **Alternative agents and management options**

- Where patients do not have sufficient supplies of their Clenil® Modulite® inhalers, patients should be supported, in the first instance, to liaise with local pharmacies directly to ascertain their stock levels as different pharmacies use a range of wholesalers.
- Where supplies of Clenil® Modulite® 100mcg are not available locally, we would recommend, where clinically appropriate either:
  - Using the Clenil® Modulite® pressurised metered dose inhalers available as 50mcg or 200mcg which may be used if clinically appropriate as a substitute to the 100mcg strength. Please consult the Summary of Product Characteristics and the British National Formulary for licensed indications and dosage requirements for the various strength of Clenil® Modulite® prior to prescribing. **Please note that the 200mcg strength is not licensed for use in children. Please note that the patient and their carers must be counselled appropriately on the change of strength and dose to avoid confusion.**
  - OR,**
  - That patients are switched to the bioequivalent device of Soprobe® metered dose inhaler (MDI)<sup>3</sup>, at their equivalent strength and dose.

- Soprobe® MDI contain the active ingredient beclometasone dipropionate within a pressurised inhalation solution (identical to that of the Clenil® Modulite® inhaler devices)<sup>3</sup>. The MHRA has approved that Soprobe® is bioequivalent to Clenil® Modulite® inhalers.



- Soprobe® MDIs are indicated for the prophylactic management of mild, moderate or severe asthma in **adults or children** (identical to that of the Clenil® Modulite® inhaler devices)<sup>3</sup>:
  - *Mild asthma*: Patients requiring intermittent symptomatic bronchodilator asthma medication on a regular basis.
  - *Moderate asthma*: Patients with unstable or worsening asthma despite prophylactic therapy or bronchodilator alone.
  - *Severe asthma*: Patients with severe chronic asthma and those who are dependent on systemic corticosteroids for adequate control of symptoms.
- Soprobe® offers the same range of strengths as Clenil® Modulite® in an equivalent inhaler (50, 100, 200 and 250micrograms per actuation)<sup>3</sup>.
- **Please note that the 200mcg and 250mcg strengths are not licensed for use in children.**
- Soprobe® device design and functionality of the inhaler are equivalent to those of Clenil® Modulite® devices<sup>3</sup>.
- Soprobe® is distributed through the mainline wholesalers: AAH, Alliance Healthcare and Phoenix plus a number of short line distributors: Day Lewis, DE Pharmaceuticals Group, Lexon and Sigma.
- Counsel the patient and their carers as appropriate about any change to their

medication BEFORE any change is made.

- Where patients are affected by the shortage of their usual Clenil® Modulite® device and you switch these patients to the newer brand of SoprobeC® inhaler, these patients may be maintained on this newer brand, where clinically appropriate, as this is the current C&P CCG formulary choice metered-dose inhaler containing standard particles of beclometasone dipropionate.
- Please note that SoprobeC® and Clenil® Modulite® devices are **NOT** interchangeable with Qvar® and Kelhale® devices. Both Qvar® and Kelhale® have extra fine particles and are approximately twice as potent as both, SoprobeC® and Clenil® Modulite®.

## **References**

1. Chiesi Limited. Summary of Product Characteristics for Clenil Modulite 50 micrograms. Last updated Dec 2018. Available: <https://www.medicines.org.uk/emc/product/6974/smhc>.
2. Personal communication with Chiesi Ltd Customer Care and company statement issued on 19<sup>th</sup> March 2020. Available at: <https://www.chiesi.uk.com/coronavirus-update-supply-of-chiesi-products> (accessed 19/03/2020).
3. Glenmark Pharmaceuticals Europe Ltd. Summary of Product Characteristics for SoprobeC 50 micrograms per actuation pressurised inhalation solution. Last updated Dec 2019. Available: <https://www.medicines.org.uk/emc/product/9806/smhc>.

## **Document prepared by and for all correspondence contact:**

Cambridgeshire and Peterborough CCG Medicines Optimisation Team. 20 March 2020 and updated 1<sup>st</sup> April 2020; email: [CAPCCG.prescribingpartnership@nhs.net](mailto:CAPCCG.prescribingpartnership@nhs.net)

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